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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,516	10/01/2003	W. Gary Erwin	036806.00438	8336

7590 10/26/2009
Louis C. Dujmich
Ostrolenk, Faber, Gerb & Soffen, LLP
1180 Avenue of the Americas
New York, NY 10036-8403

EXAMINER

NGUYEN, TRAN N

ART UNIT	PAPER NUMBER
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3626

MAIL DATE	DELIVERY MODE
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10/26/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/676,516	Applicant(s) ERWIN, W. GARY	
	Examiner Tran Nguyen	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 7-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1-6 in the reply filed on 09/21/2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

This application contains claim(s) 7-15 drawn to a nonelected species. A complete reply to the restriction must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

Therefore, claim(s) 7-15 is/are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Response to Amendment

As per the Office Action mailed 01/07/2009:

The rejection of claims 1-15 under 35 USC 101 is hereby withdrawn in view of Applicant's amendment to claims 1, 6, and further in view of Examiner's withdrawal of claims 7-15.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim(s) 1, 3-6 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over McIlroy (5953704).

As per claim 1, McIlroy teaches a method (column 3 line 3) capable of:

- (a) being implemented on computer (Figure 1);
- (b) improving the treatment of a patient (Abstract);

the method comprising:

(a) storing a data structure comprising fields for patient vital data (reads on "key medical characteristics" and "vital statistics") (Figure 2a-8b).

Insofar as the remainder of the claim is concerned, the applied art need not teach these limitations in view of the optional limitations recited therein.

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McIlroy further teaches:

- (a) sending data over network (column 4 line 55);
- (b) creating an evidence chart (Figure 9a label 4);
- (c) storing the data in the system (Figure 9a);
- (d) creating software logic based on a steering committee (reads on "accepted medical teachings, medical standards and protocols") and evidence chart (reads on "structured electronic population data") (Figure 9a);
- (e) obtaining the patient's data (Figure 14);
- (f) analyzing the patient's data based on the software logic (Figure 15);
- (g) proposing a treatment for the patient (Figure 16).

While some of the steps in McIlroy may be manually performed and the results stored in the system, the difference between the applied art and the claimed automated steps do not result in a patentable difference.

In particular, McIlroy teaches that it is well within the level of ordinary skill in the art to automate medical decisions (Abstract and throughout).

Therefore, at the time the invention was made, it would have been obvious to automate the manual steps of McIlroy with the motivation of automating known manual processes. *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958).

As per claims 3-4, McIlroy teaches following up with the patient and adjusting the treatment as needed (Figure 9a label 12).

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As per claim 5, McIlroy teaches revising the system logic based on feedback from the field (column 18 line 53-61).

As per the set of claim(s): 6, this set of claim is rejected for substantially the same rationale as applied to the rejection of the set of claim(s): 5, respectively, and incorporated herein.

Claim(s) 2 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over McIlroy as applied to parent claim 1 above, and further in view of Applicant Admitted Prior Art (AAPA).

As per claim 2, McIlroy does not teach "de-identifying".

Page 6 of the specification discloses:

[0019] Data-gathering step 115 may optionally include de-identification of the data in any conventional manner to achieve compliance with any applicable patient privacy regulations, such as those found in the U.S. Health Insurance Portability and Accountability Act ("HIPAA"). In particular, 45 C.F.R. Parts 160 and 164 of the Act relate to standards for the privacy of individually-identifiable health information (the "Privacy Rule"), promulgated by the Department of Health and Human Services (HHS). In part the Privacy Rule can restrict the acquisition and use of certain types of patient data, particularly individually-identifiable health information.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the teachings of 45 CFR 160, 164 within the embodiment of McIlroy with the motivation of legal compliance.

Response to Arguments

Applicant's arguments filed 04/13/2009 have been fully considered but they are not persuasive.

Applicant's arguments with respect to claims 1,6 on page 9-10 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The new ground(s) of rejection presented in this Office action, if any, was/were necessitated by Applicant's amendment. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tran (Ken) N. Nguyen whose telephone number is 571-

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270-1310. The examiner can normally be reached on Monday - Friday, 9:00 am - 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, C. Luke Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/T. N./

Examiner, Art Unit 3626

10/14/2009

/C. Luke Gilligan/

Supervisory Patent Examiner, Art Unit 3626